DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9202d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 2916905

November 29, 2001

Carmelo J. Tringali, President
Monterey Fish Co., Inc.
840 Fir Avenue
Sand City, California 93955

WARNING LETTER

Dear Mr. Tringali:

On August 30, 2001, we inspected your seafood processing facility located at 840 Fir Avenue, Sand City, California and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your mackerel, sardines, mahi mahi, tuna, and escolar and your imported octopus and crabmeat to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout, which gives information on how to obtain the *FDA Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001.*

Your serious HACCP deviations are as follows:

1. a. You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for frozen mackerel and frozen sardines lists critical limits at the receiving critical control point as follows:

   - Temperature less than 45°F:
     This critical limit is not adequate to control the food safety hazard of histamine formation at receipt by the primary processor as the temperature of the fish should be controlled at 40°F or less.

- No off odors:
  This critical limit is not adequate because it does not specify a maximum and/or minimum value to which histamine formation can be controlled at the receiving critical control point. An adequate critical limit includes the number of off odor fish allowable per incoming lot (e.g., no more than 3 fish in a sample of 118 fish may show signs of decomposition).

- Caught within last 24 hours & iced:
  This critical limit is not adequate because it does not specify that the incoming fish was held at 40°F or less.

b. Your firm's HACCP plan for mahi mahi, tuna, and escolar lists the following critical limits at the receiving critical control point that are not adequate to control the food safety hazard of histamine formation due to time/temperature abuse:

   - Temperature not more than 40°F

   - No off odors:
     This critical limit is not adequate because it does not specify a maximum and/or minimum value to which histamine formation can be controlled at the receiving critical control point. An adequate critical limit includes the number of off odor fish allowable per incoming lot (e.g., no more than 3 fish in a sample of 118 fish may show signs of decomposition).

Please refer to Chapter 7, Step #14, "For receipt by primary (first) processor," in the *FDA Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001*, a copy of which is enclosed for your ready reference.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plans for mahi mahi, tuna, and escolar at the receiving and refrigerated storage critical control points to control histamine is not appropriate. Icing fish above 40°F, but less than 45°F, would not prevent adulterated product from entering commerce. You need to evaluate the total exposure time of the fish to elevated temperatures. Please refer to Chapter 7, STEP #16, "For receipt by secondary processor," in the *FDA Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001.*

3. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for octopus imported from the [redacted] and for crabmeat imported from [redacted]

4. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the Seafood HACCP regulations to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed

an affirmative step of maintaining on file a copy of the foreign processor's HACCP plan and a written guarantee from the foreign processor that the imported fish or fishery product was processed in accordance with the Seafood HACCP regulations for octopus distributed by [redacted] in the [redacted] that was not adequate. [redacted] has not provided a written copy of their HACCP plan, and the written guarantee has expired-- it was valid only until December 31, 2000.

We observed some of the above-mentioned HACCP deviations during the previous FDA inspection of your facility on June 8, 9, and 16, 2000. We discussed the deviations with you at the conclusion of the inspection, and you promised corrections.

At the conclusion of the current inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Anthony Tringali, Vice President of Operations. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as copies of the HACCP plans or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

Dennis K. Linsley
District Director
San Francisco District